REMARKS

The Official Action dated December 3, 2003 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claims 1, 4-14 and 19 remain in the application and have been amended as to matters of form. Claims 1 and 4 have additionally been amended to clarify the limitations recited therein. Claims 13 and 14 have been amended into independent form. Claim 63 is added. Support for claim 63 may be found throughout the specification and in claim 1. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

Claims 1, 4-14 and 19 were rejected under 35 U.S.C. §112, first paragraph, as not being enabled by the specification. Specifically, the Examiner asserted that while the specification is enabling for a method for treating conditions associated with lipid oxidation comprising administering apolipoprotein A-IV compound, the specification does not reasonably provide enablement for a method for treating conditions associated with lipid oxidation comprising administering all apolipoprotein A-IV variants.

This rejection is traversed with respect to present claims 1, 4-14 and 19 and reconsideration is respectfully requested. More particularly, claim 1 recites a method for inhibiting lipid oxidation associated with a condition in a patient. The method comprises administering to a patient a composition comprising a pharmacologically effective amount of an apolipoprotein (apo) A-IV peptide or derivative, analog, homolog, or fragment thereof, to inhibit lipid oxidation. The apolipoprotein A-IV peptide is from 6 to 71 amino acids in length. The peptide or derivative, analog, homolog, or fragment thereof has substantially the same lipid oxidation properties as the apolipoprotein A-IV molecule.

Claim 13 recites a method of inhibiting the progression of atherosclerosis in a patient in need thereof. The method comprises administering to the patient a composition comprising an effective anti-oxidation amount of an apolipoprotein (apo) A-IV peptide or derivative, analog, homolog, or fragment thereof, to inhibit the progression of atherosclerosis. The apolipoprotein A-IV peptide is from 6 to 71 amino acids in length. The peptide or

derivative, analog, homolog, or fragment thereof has substantially the same lipid oxidation properties as the apolipoprotein A-IV molecule.

Claim 14 is directed to a method of treating a patient for atherosclerosis. The method comprises administering to the patient a composition comprising an effective anti-oxidation amount of an apolipoprotein (apo) A-IV peptide or derivative, analog, homolog, or fragment thereof, to inhibit the progression of atherosclerosis. The apolipoprotein A-IV peptide is from 6 to 71 amino acids in length. The peptide or derivative, analog, homolog, or fragment thereof has substantially the same lipid oxidation properties as the apolipoprotein A-IV molecule.

Thus, the peptides and their derivatives, analogs, homologs and fragments for use in the present methods, while not being the apolipoprotein A-IV molecule, have substantially the same lipid oxidation properties as the apolipoprotein A-IV molecule. As a matter of Patent Office practice, a specification disclosure which contains a teaching of a manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of section 12 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support, *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (CCPA 1971) (emphasis by Court). The Examiner has not provided any objective evidence of record that the present claims are not enabled by the specification.

The Examiner further asserted that the specification indicates at pages 6, lines 3-6 that a number of novel lipid oxidation suppressant peptides, derived from apolipoprotein (apo) A-IV, have been made but the peptides are not adequately described or demonstrated in the specification. This assertion is inaccurate as the specification clearly describes and demonstrates apolipoprotein A-IV peptides and their derivatives, analogs, homologs or fragments. For example, the specification at pages 15-21 lists numerous apo A-IV peptides and apo A-IV peptide analogs. Moreover, the specification clearly defines peptides and their derivatives, analogs, homologs and fragments as having the same or substantially the same lipid oxidation properties as the apolipoprotein A-IV molecule (see the definitions on page 12, lines 2-4 (peptide); page 6, lines 14-16 (homologue); page 6, lines 16-19 (analog); page 22, line 23--page 23, line 2 (derivative); and page 23, lines 16-18 (fragment). Furthermore,

as noted by the Examiner, the specification outlines several art-recognized procedures for producing such apo A-IV peptides and their derivatives, analogs, homologs or fragments (see, for example, pages 24-26). Thus, it is clear that the specification adequately describes and demonstrates apo A-IV peptides and their derivatives, analogs, homologs or fragments.

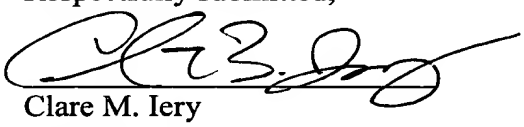
The Examiner further asserted that the specification does not provide any specific guidance or treating conditions, such as patient population, dosage regimen, routes of administration, the time and treatment schedule, etc. This assertion is also inaccurate. Specifically, the specification discloses: the patient population at page 13, lines 7-9 as being "a warm-blooded animal or mammal which is in need of treatment for a choric heart disease, atherosclerosis, hypercholesterolemia or which is in need of inhibiting oxidation"; a dosage regimen at page 26, lines 16-20; and lists numerous routes of administration at pages 26-31. Furthermore, claims 8-12, respectively, are specifically directed to routes of administration, dosage regimen and time schedules.

A disclosure is enabling if, from the information set forth in the specification, coupled with information known in the art, one of ordinary skill in the art could make and use the invention without undue experimentation, *United States v. Teletronics, Inc.*, 8 U.S.P.Q.2d 1217, 1224 (Fed. Cir. 1988). Moreover, every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification; rather, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention, *Genetech v. Novo Nordisk, A/S,* 42 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1997). Furthermore, Applicants are not required to disclose every embodiment encompassed by their claims, even in an unpredictable art. *In re Angstadt,* 190 U.S.P.Q. 214 (CCPA 1976). As the specification clearly defines apo A-IV peptides and their derivatives, analogs, homologues and fragments, and the Examiner has not provided any objective evidence of record that the present claims are not enabled, the present specification must be taken as in compliance with 35 U.S.C. §112, first paragraph, *In re Marzocchi*, 169 USPQ 367 (CCPA 1971).

It is therefore submitted that present claims 1, 4-14 and 19 are fully enabled by the specification, whereby the rejection under 35 U.S.C. §112, first paragraph, has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the Examiner's rejection of the claims under 35 U.S.C. §112, first paragraph, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



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